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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,336

11/27/2006

Kenji Nagakawa

10921.363USWO

1215

52835

7590

10/22/2010

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EXAMINER

SAKELARIS, SALLY A

ART UNIT

PAPER NUMBER

1773

MAIL DATE

DELIVERY MODE

10/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,336	<b>Applicant(s)</b> NAGAKAWA ET AL.	
	<b>Examiner</b> SALLY A. SAKELARIS	<b>Art Unit</b> 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-10 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-10, and 16-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/13/2010 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

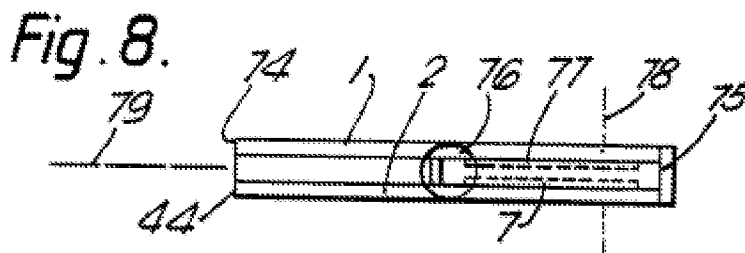
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5-10, and 16-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shanks et al. (WO 86/00141).

With regard to claims 1 and 16, Shanks teach an electrode free analyzing tool comprising: a reaction space in which a particular component of a sample and a reagent react with each other (within (1)) ; and a reagent portion ((7) and (77)) which is arranged in the reaction space (1) and which dissolves when the sample is supplied to the reaction space (1); wherein the reagent portion includes a first part (7) and a second part (77) facing each other, both capable of holding or retaining a reagent thereon and provided on a defining surface defining the reaction space (i.e., that space between (7) and (77) (Pages 23 and 24). It should be noted that

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the applicant's recitation of "is measured by colorimetry" in claim 16 will be interpreted by the office as intended use language but notwithstanding the device is interpreted as being capable of being detected with the use of colorimetry. Furthermore, it should be noted that Shanks teaches a color developing reagent in their immobilization and labeling with fluorescent ligands or dyes such as cibacrom blue, which specifically binds fluorescent and unlabelled albumin or other proteins (Page 11 lines 15-35) (Pg. 4 lines 1-15). Inherent in this teaching then is the substrate's capability for being detected with luminescent or colorimetric assays.



With regard to claim 2, the first part (7) and second part (77) are separated from each other.

With regard to claim 3, the first part and the second part differ in composition (Page 24 lines 334-36).

With regard to claims 5, 6, 16-19, the facing distance between (7) and (77) is taught to lie within a broad range of widths such as 10 $\mu$ m – 1000 $\mu$ m which includes widths that are therefore not greater than 300 $\mu$ m, 150  $\mu$ m, 100  $\mu$ m, or 75  $\mu$ m and not smaller than 30 $\mu$ m (Pages 6 and 8).

With regard to claims 7 and 22, the analyzing tool of claim 5 and 16 is further comprised by a first plate (7) and a second plate (77) both defining the reaction space and including respectively the first and second parts/regions (i.e., each part consists of a characteristic reactive

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layer, and if needed for the purposes of a particular test, an auxiliary reagent can be provided as a releasable coating that can dissolve in the sample liquid drawn into the cell) (Pg. 22 lines 4-26).

With regard to claims 8 and 23, the above structure includes a spacer (76) which defines the reaction space (i.e., that which is between (7) and (77)) creating the facing distance.

With regard to claims 9, 10, 20, 21, and 24 blood is used as a sample which is moved through the microchannel by way of capillary action (Page 4, line 30-35 for example).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-3, 5-10, and 16-24 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SALLY A. SAKELARIS whose telephone number is (571)272-6297. The examiner can normally be reached on Monday-Friday 8-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 5712721267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sally A Sakelaris/  
Examiner, Art Unit 1773  
10/21/2010